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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,533	01/30/2006	Dong Liang	514572000500	4778
25225 7590 05/10/2011 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040				
EXAMINER				
BASS, DIRK R				
ART UNIT		PAPER NUMBER		
1777				
NOTIFICATION DATE		DELIVERY MODE		
05/10/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOOfficeSD@mofo.com
PatentDocket@mofo.com
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Office Action Summary**Application No.**

10/537,533

Applicant(s)

LIANG ET AL.

Examiner

DIRK BASS

Art Unit

1777

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 21, 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-18,22-25,27,28,48,49 and 52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,3-8,10-18,22-25,27,28,48,49 and 52 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No.(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed March 21, 2011 is acknowledged. Claims 1, 3-8, 10-18, 22-25, 27-28, 48-49, and 52 are pending and further considered on the merits.

Response to Amendment

In response to the amendments, the examiner modifies the grounds of rejection set forth in the office action dated March 10, 2010.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-8, 10-25, 27-28, 48-49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Craig, US 5792943 (Craig, IDS) in view of Goedert, US 4935040 (Goedert, IDS) and Manginell, US 6666907 (Manginell).

Regarding claims 1 and 3, Craig discloses a gas chromatograph column (col. 12, l. 54 – col. 13, l. 1), which column comprises more than two lid layers and more than one channel layer (col. 4, l. 41-47 and fig. 6a-6b), wherein each of said layers comprises a compact material (see “substrate material”, col. 5, l. 1-8) suitable for gas chromatography (col. 12, l. 54 – col. 13, l. 1), said channel layers comprise microfabricated channels on both sides (col. 17, l. 8-11, and fig. 6a-6b) and a side of said lid layers form at least four capillaries (see “channel 260”, “channel 262”, fig. 6a-6b and col. 4, l. 41-47), said at least four capillaries are connected to each other through a hold in said channel layer to form an integrated capillary (see “conduit means 272”, fig. 6a-6b), said integrated capillary is connected to outside atmosphere on both ends via

holes on two outmost lid layers (implicitly disclosed in fig. 6a-6b) to serve as an inlet and an outlet (see “aperture 270”, “aperture 278”, fig. 6a-6b), and wherein the wall of the integrated capillary is coated with a thin film of a stationary phase (see “surface treatment”, col. 13, l. 42-54 and Example 1, col. 20, l. 33-35).

Claim 1 recites a limitation regarding a manipulative step to bring about a specific product, i.e. coating the capillary wall before binding lid and channel layers together. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

Alternatively, it would have been obvious to a routineer in the art to coat the column prior to assembly since doing so is well known in the art as evidenced by Manginell. Manginell discloses a fabrication process for a miniature chromatography column wherein the stationary phase is applied before the layers are bonded together in order to achieve a uniform coating throughout the chromatography column (col. 4, l. 60 - col. 5, l. 9).

Craig fails to explicitly disclose a gas chromatograph column wherein said lid layers and channel layers are discrete lid and channel layers.

Goedert discloses a miniature gas chromatography column (abstract) comprising a plurality of discrete lid and channel layers (fig. 1) in order to form a unitary

body having aligned chromatographic micro-columns (col. 4, l. 61-64) and to allow separate fabrication of said lid and channel layers (implicitly disclosed).

At the time of invention, it would have been obvious to combine the discrete lid and channel layer teachings of Goedert with the gas chromatograph column of Craig to allow separate fabrication of said lid and channel layers, thereby increasing the scale and ease of production of such gas chromatograph columns.

Furthermore, while Craig fails to explicitly disclose discrete lid and channel layers, it would have been obvious to one having ordinary skill in the art at the time of invention to separate the lid and channel layers of Craig, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art (MPEP 2144.04, Section V, Part C).

Regarding claims 4-5, Craig in view of Goedert discloses a gas chromatograph column wherein the compact material is metal wherein the lid layers and the channel layers comprise the same compact materials (see "substrate material", col. 5, l. 1-8).

Regarding claims 6-7, while Craig teaches miniaturization of gas chromatograph columns being advantageous due to reduced production costs, decreased instrument sizing, and increased speed of analysis (col. 1, l. 14-22), Craig fails to explicitly disclose a gas chromatograph column wherein the lid layers and channel layers have an area ranging from about 1 to about 100 cm².

Goedert discloses a gas chromatography column wherein the lid layers and channel layers (see "structure 14" and "wafer group 39", fig. 1) have an area ranging from about 1 to about 100 cm² (see "5cm x 5cm", col. 4, l. 41-43) to simplify

manufacturability of parts and to reduce further size, weight, and electrical consumption of instruments utilizing miniaturized gas chromatograph columns (col. 1, l. 67—col. 2, l. 5). It is construed by the examiner that “6mm” can reasonably be within the range of “about 5mm” due to an increase of thickness (20%) being less than a degree of magnitude from the claimed range of “about 5mm”.

At the time of the invention, it would have been obvious to one skilled in the art to combine the teachings of Craig and Goedert to simplify manufacturability of parts and to reduce further size, weight, and electrical consumption of instruments utilizing miniaturized gas chromatograph columns

Regarding claim 8, Craig in view of Goedert discloses a gas chromatograph column wherein the lid layers and the channel layers have the same or different area (fig. 6a-6b).

Regarding claims 10-11, Craig in view of Goedert discloses a gas chromatograph column wherein the microfabricated channels have a width ranging from about 1 to about 1,000 microns (see “5 to 1000 micrometers”, col. 10, l. 6-9) and a depth ranging from about 3 to about 500 microns (see “50-800 micrometers”, col. 17, l. 49-54).

Claims 12-13 recite limitations regarding a manipulative step to bring about a specific product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art,

the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

Regarding claim 14, Craig in view of Goedert discloses a gas chromatograph column wherein the integrated capillary has a total length of at least 4 meters (see "path lengths of up to 15 meters", col. 17, l. 49-54).

Regarding claim 15, Craig in view of Goedert discloses a gas chromatograph column wherein the integrated capillary has a semi-circular sectional shape (fig. 12).

Regarding claim 16, Craig in view of Goedert discloses a gas chromatograph column wherein the cross-section of the integrated capillary has an area ranging from about 5 to about 250,000 square microns (see "50-800 micrometers", col. 17, l. 49-54). The reference teaches diameter dimensions between the range of 50 and 800 micrometers. Selecting a diameter of 50 micrometers and computing the area of a circular cross section equates to a cross-sectional area of approximately 7854 square micrometers.

Regarding claim 17, Craig in view of Goedert discloses a gas chromatograph column wherein the integrated capillary has identical cross-section areas along its length (fig. 2).

Regarding claim 18, Craig in view of Goedert discloses a gas chromatograph column wherein the integrated capillary has a serpentine pattern (fig. 6a).

Regarding claim 22, Craig in view of Goedert discloses a gas chromatograph column wherein the hole in the channel layer and the holes in the lid layers have a round shape (fig. 6a).

Regarding claim 23, Craig in view of Goedert discloses a gas chromatograph column wherein the hole in the channel layer and the holes in the lid layers are formed by etching (col. 3, l. 57-67).

Regarding claim 24, Craig in view of Goedert discloses a gas chromatograph column wherein the layers are bound together by heat bonding (col. 4, l. 51-64).

Regarding claim 25, Craig fails to explicitly disclose a gas chromatograph column further comprising a heater wire deposited on an outside surface of the integrated capillary to provide for electric heating of a stationary phase material within the integrated capillary during operation of a gas chromatograph.

Goedert discloses a heater wire (see "column heater #1", fig. 1 and "hot wire resistive element 166", fig. 9) deposited on an outside surface of the integrated capillary to provide for electric heating of a stationary phase material within the integrated capillary during operation of a gas chromatograph (col. 7, l. 40-52) in order to provide a heating apparatus that is electrically controlled for selective heating of a stationary phase material within the integrated capillary (col. 8, l. 26-28).

At the time of the invention, it would have been obvious to one skilled in the art to combine the heater wire of Goedert with the gas chromatography column of Craig in order to provide a heating wire that is electrically controlled for selective heating of a stationary phase material within the integrated capillary.

Regarding claims 27-28, Craig in view of Goedert is relied upon in the rejection of claim 1 as set forth above.

Regarding claims 48-49, Craig in view of Goedert disclose a gas chromatography column wherein the compact material is silicon (col. 6, l. 47-55) and said lid and channel layers comprise different compact materials (implicitly disclosed in col. 6, l. 6-60).

Regarding claim 52, Craig fails to explicitly disclose a gas chromatograph column wherein the lid layers and channel layers have a thickness ranging from about 0.1 to about 5mm.

Goedert discloses a gas chromatography column wherein the lid layers and channel layers (see "structure 14" and "wafer group 39" , fig. 1) have a thickness ranging from about 0.1 to about 5mm (see "6mm", col. 4, l. 41-43) to simplify manufacturability of parts and to reduce further size, weight, and electrical consumption of instruments utilizing miniaturized gas chromatograph columns (col. 1, l. 67—col. 2, l. 5). It is construed by the examiner that "6mm" can reasonably be within the range of "about 5mm" due to an increase of thickness (20%) being less than a degree of magnitude from the claimed range of "about 5mm".

At the time of the invention, it would have been obvious to one skilled in the art to combine the teachings of Craig and Goedert to simplify manufacturability of parts and to reduce further size, weight, and electrical consumption of instruments utilizing miniaturized gas chromatograph columns.

Response to Arguments

Applicant's arguments filed November 9, 2009 have been fully considered but they are not persuasive.

Applicant continues to argue that the recited prior art does not teach the aspect of applicant's invention drawn to coating a stationary phase prior to assembly of a micro-miniature chromatography column. In response, the examiner reminds applicant that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113). In this case, the product is taught by Craig in view of Goedert, having a stationary phase coating within the micro-miniature chromatography column (see rejections above).

Furthermore, in order for a product by process limitation to be given patentable weight, there must be evidence that the product formed is materially different than the prior art. Applicant has failed to provide any evidence that the process produces any advantageous result, or is in fact structurally different than that disclosed in the prior art. Reciting that the process is advantageous and maintains sharp separation peaks during separations is insufficient. Applicant does not provide evidence that the claimed process directly results in sharp separation peaks.

Moreover, the examiner has provided prior art concerning separation columns in which the recited process is used to coat the capillary column before combining the lid and channel layers. Applicant argues that Manginell does not disclose depositing the stationary phase on the walls of the channels. However, the examiner maintains that

Manginell applies the stationary phase onto the walls prior to the attachment of the lid and channel layer thereby obviating the process step.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1777

/DRB/
Dirk R. Bass